CDISC Roadmap
Focus on Realizing the Long-Term Vision

Peter Van Reusel, Chief Standards Officer, CDISC

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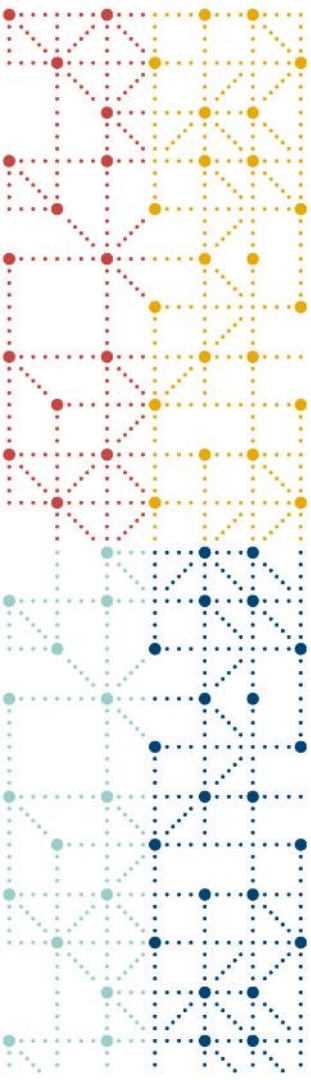
Agenda

- The Strategic Goal
- CDISC Roadmap



The Strategic Goal

Realizing the CDISC Mission

STRATEGIC GOAL

Expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results

(CDISC will expand and realize the original 360 vision)

Expand & Connect

Expand, Connect, and Digitalize our Standards

Enable & Automate

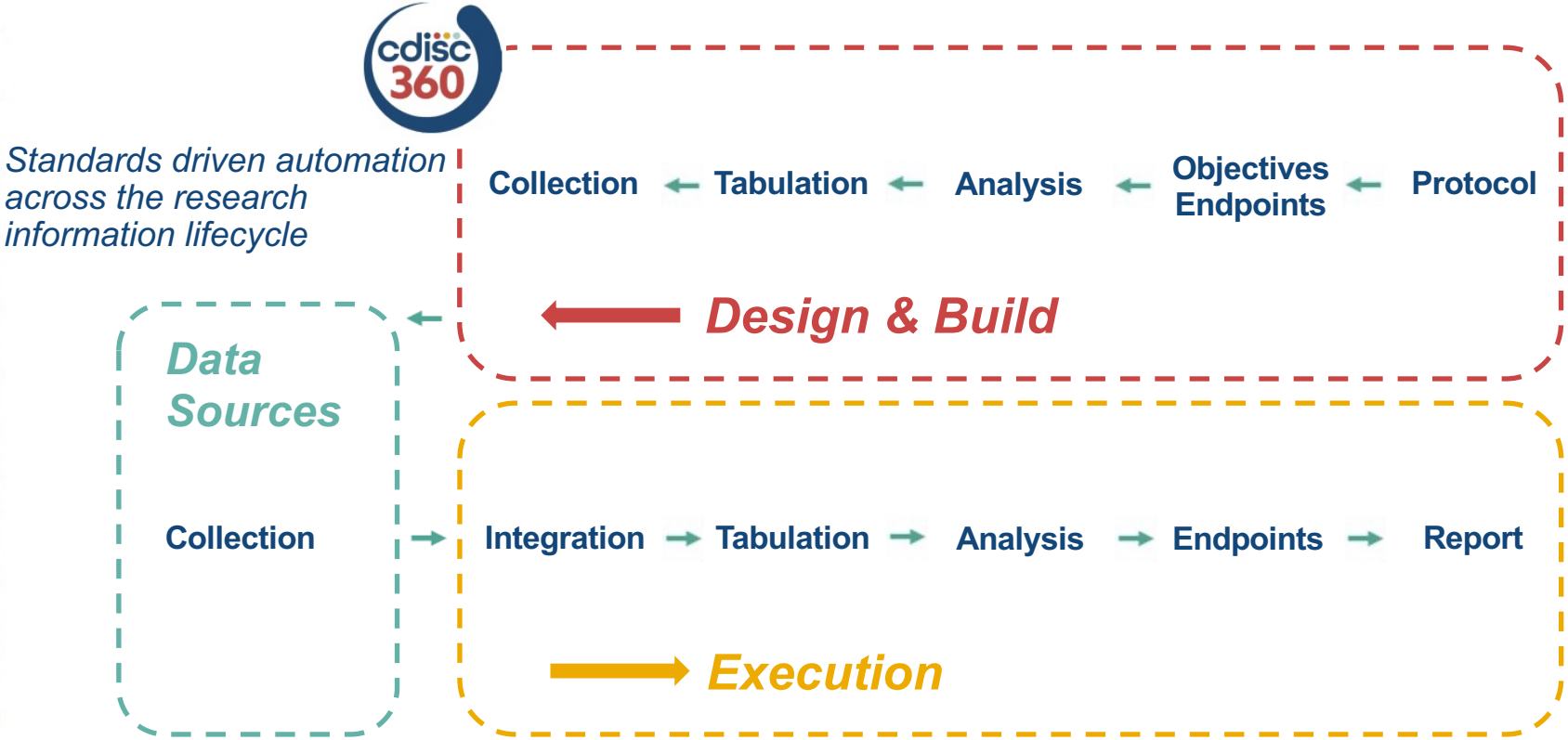
Reduce Variability, Enable Interoperability, and Increase Automation

Engage & Adopt

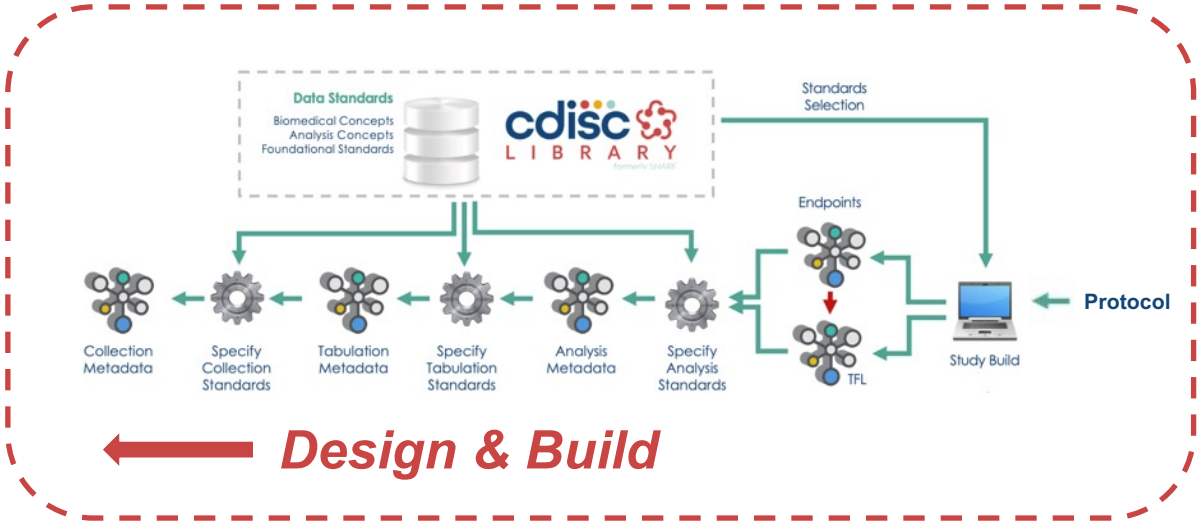
Focus on Community Needs

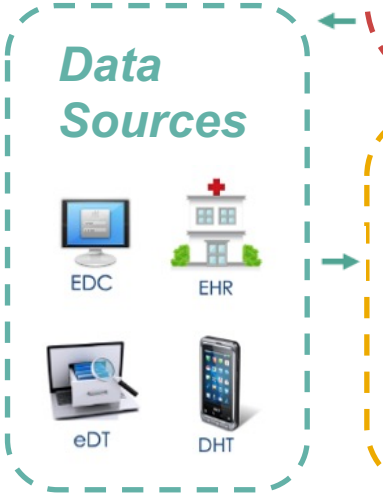
Deliver Business Value

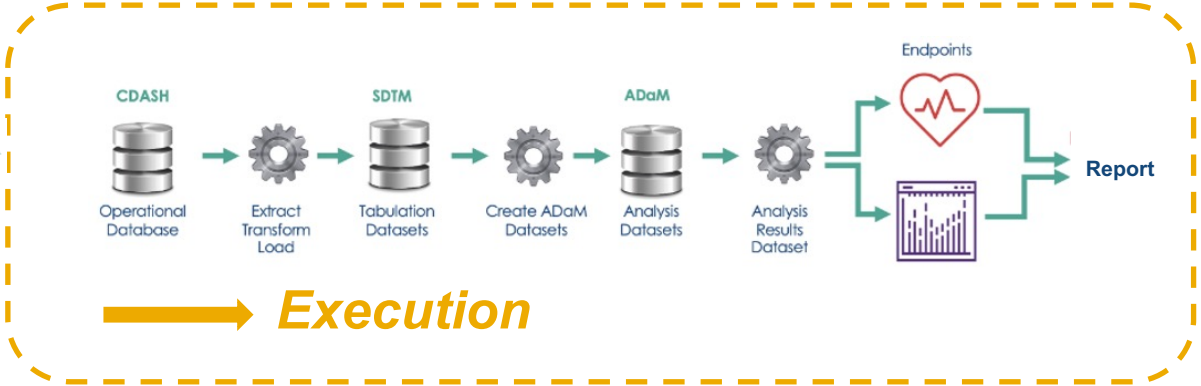
End to End Study Information Lifecycle

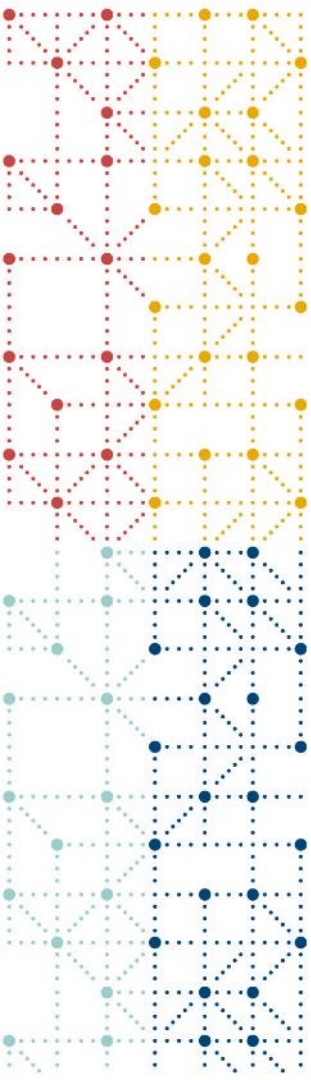


Our work has started with CDISC 360









CDISC Roadmap

Roadmap Pillars and Objectives

Expand & Connect

- Embrace and adopt digital study design
- Expand and connect standards across the clinical research information lifecycle
- Define clear pipeline for integration of new data sources

Enable & Automate

- Develop ready to use implementation standards
- Create open-source technology enabled standards
- Establish and manage a conformance framework

Engage & Adopt

- Establish a continuous feedback loop across the CDISC community
- Shift focus to producers/consumers needs and lower the barrier to use
- Prioritize communication to enable our stakeholders

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Expand & Connect: Digital Study Design

- Unified Study Definitions Model (USDM)
  - Holds many aspects of the study design
  - Facilitates interoperability between systems
  - Schedule of Activities = digital backbone of the protocol
    - Link Schedule of Activities to standard Concepts
  - Support study design activities

TransCelerate BIOPHARMA INC.

cdisc USDM UNIFIED STUDY DEFINITIONS MODEL (DDF)

Design & Build

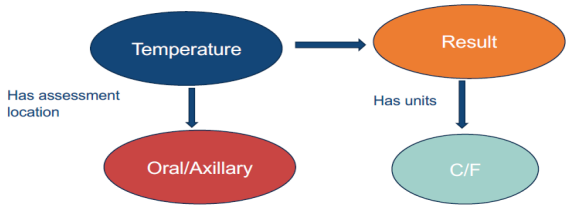
- ICH M11
  - Provide controlled terminology, aligned with USDM
  - Collaborate with ICH and Vulcan to create exchange mechanism
    - Utilizing Digital Protocol (UDP)
  - Support use cases and pilots (e.g. FDA PRISM)

ICH M11 harmonisation for better health

VULCAN HL7 FHIR

Connect Design to Results

- Mapping data from various formats often breaks down
  - The meaning and terminology do not match (e.g. eHR to SDTM)
  - Mapping between common data models is only a part of the solution
- We need well defined Concepts
  - Standardize the meaning and semantics of data
  - Regardless of data representation
- Concepts will
  - Link to the **Schedule of Activities**
  - Provide consistent implementation
  - Facilitate automation
  - Prevent AI from hallucinating



Concept

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	101.3	F	ORAL

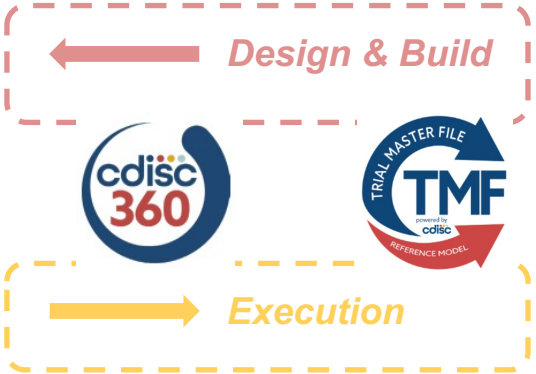
Representation

Close the gaps & Expand the standards

- Ensure standards can represent all data
  - Analysis Results Standards (launched March 2024)
  - Common electronic data transfers (to start)
  - Explore structures to represent objectives & endpoints (to start)

- TMF is now integrated with CDISC
  - Roll out form TMF standards development process
  - TMF Controlled Terminology (in progress)

- Digitalize Trial Master File
  - TMF Art of the Possible to TMF Roadmap
  - TMF systems will integrate digital protocol information
  - Enrich TMF with metadata to support automation



Expand & Connect: Integrate Sources

- Study data is originating from many sources
  - Electronic Data Capture systems and eCRFs
  - Various Data Transfers such as eCOAs, ePROs, eHRs
  - Digital Health technologies
- Provide more standards to ingest data
- Digital Health Technologies initiative
  - Partnership with DiME – Library of digital endpoints
  - Link resources to concepts, device attributes, domains
  - Standardize analysis of DHTs where applicable

cdisc DHT DIGITAL HEALTH TECHNOLOGY

DiME DIGITAL MEDICINE SOCIETY

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Expand & Connect: Integrate Sources

- Real-world data provides valuable insights but…
- Concerns about
  - Data quality
  - Data integration issues (fidelity)
  - Traceability
- RWD Lineage
  - Exchange mechanism to represent lineage, traceability and quality
  - Together with the data
- Continue partnering with NIH, IMI and other SDOs
  - Define core data elements

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Enable & Automate: Ready to Use Standards

- Provide rich resources and examples
  - normative standards with informative content
  - ‘easy’ to implement and understand

- eCRF portal
  - https://www.cdisc.org/kb
  - 70 eCRF resources and growing
  - Ready to download and use in eDC systems

- eTLF portal
  - Based on the Analysis Results Standard
  - Analysis concept + ADaM metadata + ARS metadata + TFL example
  - Ready to download and implement

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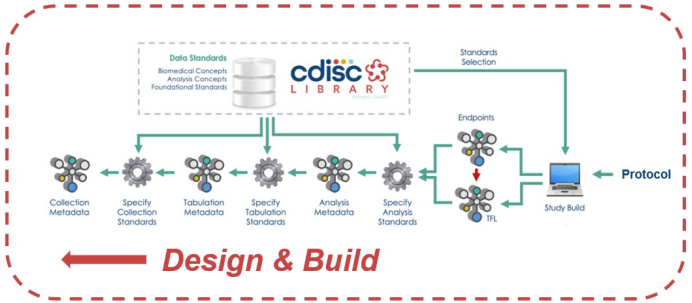
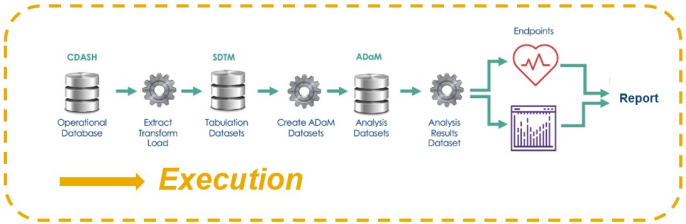
Enable & Automate: Preconfigured example study

- Complete preconfigured example study
  - Include all components from design to submission
  - Understand the normative gaps between standards



- Demonstrate and test the example study
  - Set-up Connectathon events with technology providers



- Collaborate with Regulatory to define use cases
  - Enabling better use of standards for review

Enable & Automate: Open-Source

- Consider technology and automation upfront

- CDISC Open Source Alliance
  - Support and promote development of open-source software
  - Drive innovation

- Examples
  - Oak Initiative: automate SDTM generation
  - Open Study Builder
  - CDISC Open Rules Engine
  - CDISC Rule Editor

Enable & Automate: Technology enables Automation

- Modernize data transport: Dataset JSON
  - Technology friendly, future proof

- Standards with logical models
  - Both USDM and ARS are published with logical models
  - Enables technical implementation, demonstrate use cases
  - Includes API specifications

- CDISC Library
  - Relevant standards are digitally available via APIs
  - Source for tools and automation

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Enable & Automate: Conformance Rules

- Complete conformance rules for all relevant foundational standards
  - SDTM, ADaM, SEND, ARS, …
- Expand to regulatory business rules
  - Current collaboration with FDA, other agencies to follow
- Expand to industry quality rules
  - Quality rules beyond standard conformance
  - Creating conformance rules for USDM to ensure compliance with USDM framework
    - This will enable checking conformance with M11 transport standard
- Going forward
  - Establish rules for all CDISC standards

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- Shift **focus** to **user needs** and lower the barrier to use
- Prioritize **communication** to enable our stakeholders

Engage & Adopt: Feedback

- Ensure we are **solving the right problems**
  - Understand the needs of end-users
- Establish a transparent feedback framework
- Reform the CDISC Advisory Council
  - Member input

Continuous Feedback

Define and manage community feedback loop to ensure understanding of needs

Engage & Adopt: User Focus

- Focus to enhance and accelerate standards adoption
  - A standard is only successful when used
- Include impact assessment to significant standard changes
  - Provide a rationale and value for the change
  - Provide implementation considerations where possible
- CDISC education
  - Shift from theory to hands-on experience trainings
  - I do, we do, you do

User Focus

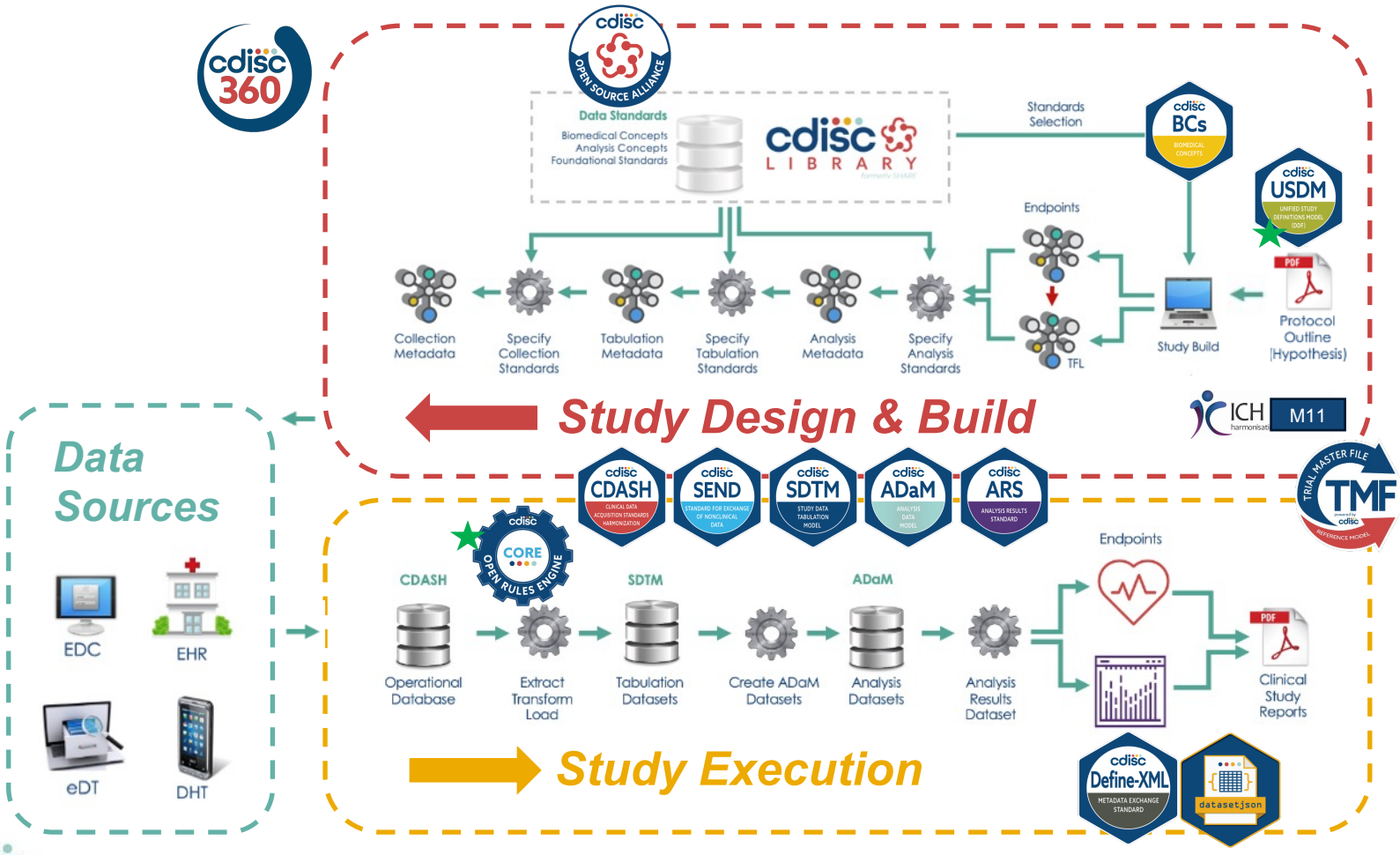
Shift from development to user needs to enhance and accelerate standards adoption

Engage & Adopt: Communication

- Evaluate on how we make content and information available
  - Website, Social Media, Github, CDISC Library
- Publish and maintain a dashboard with current CDISC activities and progress
- Publish the Annual Report
  - Summarize progress on strategic objectives
  - How is CDISC using membership fees to create value

Prioritize Communication

Create frequent and accessible information for CDISC and community alignment


cdisc 360
cdisc OPEN SOURCE ALLIANCE
Data Standards
Biomedical Concepts
Analysis Concepts
Foundational Standards
cdisc LIBRARY
Standards Selection
cdisc BCs
cdisc USDM
Endpoints
Collection Metadata
Specify Collection Standards
Tabulation Metadata
Specify Tabulation Standards
Analysis Metadata
Specify Analysis Standards
TFL
Study Build
PDF
Protocol Outline (Hypothesis)
Study Design & Build
ICH M11
cdisc CDASH
cdisc SEND
cdisc SDTM
cdisc ADaM
cdisc ARS
TRIAL MASTER FILE TMF
Data Sources
EDC
EHR
eDT
DHT
cdisc CORE OPEN RULES ENGINE
CDASH
SDTM
ADaM
Operational Database
Extract Transform Load
Tabulation Datasets
Create ADaM Datasets
Analysis Datasets
Analysis Results Dataset
Endpoints
Clinical Study Reports
Study Execution
cdisc Define-XML METADATA EXCHANGE STANDARD
datasetjson

Thank You!

We Want Your Feedback!

Opportunities:

- Contact CDISC leadership team
- Survey with QR Code
- Social post to share message with broader CDISC community
- Listening Groups